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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,585	02/08/2002	Marek Kwiatkowski	11989-008001	2835

26191 7590 05/05/2005

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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/071,585	Applicant(s) KWIATKOWSKI, MAREK	
	Examiner Frank W. Lu	Art Unit 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 1-3,6-9,14-17,19,24,25 and 35.
Claim(s) rejected: 26-28,30,31 and 34.
Claim(s) withdrawn from consideration: 4,5,10-13,18,20-23,29,32 and 33.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

DETAILED ACTION

ADVISORY ACTION

1. The proposed amendments filed on April 15, 2005 have been fully considered but will not be entered because: (1) they raise new issues that would require further consideration and/or search; and (2) they raise the issue of new matter.

Response to Arguments

I. In page 7, fourth paragraph of applicant's remarks, applicant argues the amendments have overcome objection on claims 1 and 27.

This argument has been fully considered but it is not persuasive toward the withdrawal of the objection because applicant's argument with respect to the objection is moot since applicant has amended claims 1 and 27.

II. In page 7, last paragraph bridging to page 8, second paragraph of applicant's remarks, applicant argues the amendments on claims 26, 27, 31, and 34 have overcome the rejections under 35 U.S.C 112, second paragraph.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejections because applicant's arguments with respect to the rejections are moot since applicant has amended claims 26, 27, 31, and 34.

Regarding claim 26, the proposed amendment on claim 26 raises the issue of new matter because the phrase "an oligonucleotide lacking the separation tag that was not cleaved" in the proposed amendment on claim 26 is much broader than the phrase "an oligonucleotide lacking said non-cleaved separation tag" since the separation tag that was not cleaved has an ability to be cleaved. Furthermore, the phrase "an oligonucleotide lacking the separation tag that was not

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cleaved” in the proposed amendment on claim 26 is indefinite and raises new issues that would require further consideration and/or search because it is unclear that the separation tag that was not cleaved is the first separation tag or the second separation tag.

Regarding claim 34, the proposed amendment on claim 34 raises the issue of new matter because the phrase “the separation tag that was not cleaved in step (d)” in the proposed amendment on claim 34 is much narrower than the phrase “the other separation tag”.

Furthermore, the phrase “the separation tag that was not cleaved in step (d)” in the proposed amendment on claim 34 is a new limitation and raises new issues that would require further consideration and/or search.

III. In page 8, fourth paragraph bridging to page 9, second paragraph of applicant’s remarks, applicant argues that “[A]pplicant’s specification at page 5, lines 12-14 defines a ‘separation tag’ as a chemical group or moiety bonded to an end of an oligonucleotide that allows the oligonucleotide to be separated from other oligonucleotides that lack such a tag. Present claim 30 requires a bifunctional oligonucleotide having a first separation tag at a first end of the oligonucleotide and a second separation tag at a second end of the oligonucleotide. The Kwiatkowski et al. reference discloses only monofunctional oligonucleotides that have a single separation tag on one end of the oligonucleotide. Contrary to the Examiner’s assertion, compound 16 shown in Figure 1 does not represent an oligonucleotide having a separation tag at each end. Rather, compound 16 is a CPG bead that has been activated by aminopropylsilanizing, derivatized by addition of a polythymine tract and a hydroxyalkyl group, and coupled to a disiloxyl linker, through which an oligonucleotide can be linked to the derivatized CPG support. The aminopropylsilanized CPG bead attached to the 5’ end of the polythymine tract is not a

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separation tag as defined by Applicant's specification. Rather, the CPG bead ultimately serves as the support for oligonucleotides synthesized on the disiloxyl linker. In addition, cleavage of the disiloxyl linker will not result in a 3' hydroxyl group at the 3' end of the polythymine tract. Thus, compound 16 of the Kwiatkowski et al. reference does not anticipate the presently claimed composition. Moreover, compound 17 of the Kwiatkowski et al. reference does not anticipate the presently claimed composition. In particular, the oligonucleotide of compound 17 is monofunctional in that it is linked to one separation tag - the DMTr group at its 5' end. The disiloxyl linker at the 3' end of the oligonucleotide is not a separation tag and cleavage of the disiloxyl linker would not result in a hydroxyl group at the 3' end of the oligonucleotide. Thus, the Kwiatkowski et al. reference does not disclose a composition as recited in present claim 30".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, according to the specification, "separation tag" is defined as "chemical groups or moieties bonded to either the 3' or 5' end of an oligonucleotide that allows oligonucleotides having the separation tag to be separated from other oligonucleotides that lack this function". Since CPG-based bead is a moiety bonded to 5' end of compound 16 and can be used as a separation tag to be separated from other oligonucleotides that lack a CPG-based bead, CPG-based bead on the compound 16 is a separation tag. Second, from the structure of compound 16, one of skill in the art can tell that cleavage of the disiloxyl linker from compound 16 will result in a 3' hydroxyl group at the 3' end of compound 16. Therefore, the reference from the Kwiatkowski *et al.*, discloses a composition as recited in claim 30.

2. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

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such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
May 3, 2005


FRANK LU
PATENT EXAMINER